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ELECTION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICANT : Ranger, M. et al

INVENTION : Water Soluble Stabilized Self-Assembled Polyelectrolytes

SERIAL NUMBER : 09/877,999

FILING DATE : June 8, 2001

EXAMINER : Schnizer, Richard A.

GROUP ART UNIT : 1635

OUR FILE NO. : 2267.001

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CERTIFICATE UNDER 37 CFR 1.8(a)  
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*Carly (initials), Legal Asst.*

Box Non-Fee Amendment  
Commissioner for Patents  
Washington, D.C. 20231

RESPONSE TO OFFICE ACTION OF September 27, 2002

Sir:

In response to the Office Action dated September 27, 2002  
having a shortened statutory period for response set to expire  
October 27, 2002, for which a petition for extension of time to  
November 27, 2002 is filed herewith, kindly enter the following  
response to the outstanding Requirement for Restriction:

Restriction to one of the following inventions has been  
required under 35 U.S.C. 121:

I. Claims 1-14, drawn to supramolecular assemblies, classified  
in class 525, subclass 50.

II. Claims 15-18, drawn to pharmaceutical formulations comprising a supramolecular assembly and a pharmacological constituent other than a peptide, protein or genetic material, classified in class 514, subclass 1.

III. Claims 15-18, drawn to pharmaceutical formulations comprising a supramolecular assembly and a pharmacological peptide or protein, classified in class 514, subclass 2.

IV. Claims 15-18, drawn to pharmaceutical formulations comprising a supramolecular assembly and a pharmacological genetic material, classified in class 514, subclass 44.

Claims 15-18 have been characterized as generic to a plurality of patentably distinct inventions set forth as groups II-IV. If one of these groups is elected, the Examiner has indicated that the claims will be examined to the extent that they are defined by the elected group.

Groups I-IV have been characterized as being distinct because they are structurally and functionally disparate compositions. The composition of Group I is described by the Examiner as not being a pharmaceutical formulation, thus the Examiner concludes that the Group I composition could not, by itself, be used for any pharmacological effect; however it could be used for non-pharmaceutical purposes, such as the delivery of molecules to cells in vitro.

The compositions of groups II-IV are deemed to be

pharmaceutical compositions comprising structurally and functionally distinct pharmaceutically active agents. The non-peptide, non-protein, non-genetic material component of the Group II invention is characterized by the Examiner as being structurally and functionally distinct from the peptide, protein, and genetic materials of groups III and IV. The peptides and polypeptides of group III are likewise characterized as being distinct from the genetic material of group IV because, unlike the genetic material, they cannot encode a gene product of any kind, and therefore must have a different function or mechanism of action than the genetic material.

Thus, the Examiner concludes that because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicants elect the Group I invention for further prosecution on the merits, with traverse.